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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,041	12/01/2003	Jamieson Crawford	3896-031547 (P-6059)	2967

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EXAMINER

WITCZAK, CATHERINE

ART UNIT PAPER NUMBER

3767

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/725,041	Applicant(s) CRAWFORD, JAMIESON	
	Examiner Catherine N. Witczak	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-23 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/15/05; 3/4/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, and 12-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Crawford et al (US 6,659,983).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 1: Crawford et al disclose in Figure 1 a hub having opposed proximal and distal end and a passage extending therebetween (14); an elongated shield housing having a first open end and an opposed second open end with a passageway in between (20); a needle cannula having a distal puncture tip (16) which extends from the hub housing with at least a portion of the needle cannula extending through the passageway of the shield housing; a biasing member acting on the shield housing to bias the shield toward a second position covering the distal puncture tip of the needle cannula (22); and an engagement mechanism (12) in releasable engagement with the shield housing (50) which maintains the shield housing in the first biased position adjacent the hub housing and when engaged, releases the shield housing allowing it to move toward the second position.

Claim 2: Crawford et al disclose in Figure 1 a first member extending dorsally from the hub housing (40), a second member extending from a portion of

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the first member (44), with the second member moveable with respect to the first member so as to release from engagement with the shield housing (column 3, lines 22-26).

Claim 3: Crawford et al disclose in Figure 1 a latch element extending dorsally from the shield housing (50) including a recess or opening (52) for engagement with the engagement mechanism of the hub housing.

Claim 4: Crawford et al disclose in Figure 1 the second member of the engagement mechanism (44) having a hook element (48) for engagement with the recess of the latch element.

Claim 5: Crawford et al disclose in Figure 1 the second member of the engagement mechanism (44) connected to the first member of the release mechanism (40). Furthermore, Crawford et al disclose in column 3 lines 7-8 that the connection between the two allows for resilient deflection of the second member, wherein this description reads on the connection of the first (40) and second (44) members being a fulcrum.

Claim 6: Crawford et al disclose in Figure 1 first (40) and second (44) member of the engagement mechanism including corresponding surfaces for movement toward each other about the fulcrum, and further disclose in column 3, lines 21-26 that this releases the hook element from the recess/opening of the latch element.

Claim 7: Crawford et al disclose in column 2, lines 6-11 that the hub housing comprises structure for attachment to a medical device.

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Claim 8: Crawford et al disclose in column 3, lines 15-17 the use of a compression spring as a biasing member.

Claim 9: Crawford et al disclose in column 3, lines 10-11 shield housing extending within the passageway of hub housing.

Claim 12: Crawford et al disclose in Figure 1 a set of wings extending from opposing lateral sides of hub housing (66). Furthermore, in column 1, lines 14-16, Crawford et al disclose that these wings are flexible.

Claim 13: Crawford et al disclose in Figure 1 the engagement mechanism (40) extending dorsally from the hub housing (14) bisecting the flexible wings (66). Furthermore, Crawford et al disclose in column 3, lines 20-22 a method of activation of the engagement mechanism which would not be possible to achieve simply by bending the flexible wings toward a dorsal position.

Claim 14: In Figure 1, Crawford et al disclose a safety needle system comprising: a hub housing (14) including a needle cannula extending from a distal end of hub housing toward a distal puncture tip (column 1, lines 66-67), a shield housing covering at least a portion of the needle cannula adjacent to the hub housing (20); a biasing element (22) for biasing the shield housing toward a shielding position fully covering the puncture tip of the needle cannula (column 3, lines 25-26), and a latch mechanism (44) extending dorsally from the safety needle system for maintaining the shield housing in a biased state adjacent to hub housing. Furthermore, Crawford et al disclose withdrawing the safety needle system from a patient by grasping the latch mechanism to release shield housing from biased state to the shielding position in column 3, lines 19-26.

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Claim 15: Crawford et al disclose in Figure 1 a set of wings extending from opposing lateral sides of hub housing (66). In column 1, lines 14-18, Crawford et al disclose that these wings are flexible and insertion of the needle system comprises bending the wings to a dorsal position for guiding the needle cannula into the patient.

Claim 16: Crawford et al disclose in Figure 1 the engagement mechanism (40) extending dorsally from the hub housing (14) bisecting the flexible wings (66). Furthermore, Crawford et al disclose in column 3, lines 20-22 a method of activation of the engagement mechanism which would not be possible to achieve simply by bending the flexible wings toward a dorsal position.

Claim 17: Crawford et al disclose in Figure 1 a latch mechanism comprising a first member (40) extending dorsally from hub housing, and second member (44) connected to the first member. Furthermore, Crawford et al disclose in column 3 lines 7-8 that the connection between the two allows for resilient deflection of the second member, wherein this description reads on the connection of the first (40) and second (44) members being a fulcrum. Figure 1 also discloses second element (44) and shield housing including a latching engagement structure (52). Withdrawing step, including subsequent extension of shield housing, involving pivoting of second member about the fulcrum is disclosed in column 3, lines 21-26

Claim 18: Crawford et al disclose in Figure 1 a structure for latching engagement (12) comprising a hook element (48) extending from second

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member (44) in engagement with a recess or opening (52) within a dorsally extending portion of shield housing (50).

Claim 19: Crawford et al disclose in column 3, lines 33-35 the shield housing being prevented from re-exposing the distal puncture tip of the needle cannula once the shield housing has been extended to shielding position.

Claim 20: Crawford et al disclose in Figure 1 distal (20) and proximal (14) dorsal housing, wherein the proximal dorsal housing portion supports a needle (column 1, lines 66-67). In Figure 2, Crawford et al disclose the distal dorsal housing portion (20) as being extendable in an axial direction from the first position as shown in Figure 1, to a second position covering a distal tip of the needle. In Figure 1, Crawford et al also discloses a planar wing structure (66) integral to the proximal housing portion (14) wherein the planar wing structure extends normal to the housing. Crawford et al further disclose in Figure 1 a biasing element (22) extending between distal and proximal dorsal housing. Figure 1 also discloses a release element (40 and 50) so retaining the distal dorsal housing.

Claim 21: Crawford et al disclose in Figure 1 release element (40 and 50) comprising a release latch (48) and a receiving element (52) for receiving the latch.

Claim 22: Crawford et al disclose in Figure 1 a release latch (48) that is integral with the proximal dorsal housing portion (14)

Claim 23: Crawford et al disclose in Figure 1 a receiving element (52) comprising a recess or opening.

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Allowable Subject Matter

Claims 10 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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